

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Christopher T. Boyle, Denes Marton, and Christopher E. Banas

SERIAL NO.: 10/672,695 EXAMINER: Christopher D. Prone

FILING DATE: 09/26/2003 A.U.: 3738

TITLE: IMPLANTABLE GRAFT AND METHODS OF MAKING SAME

DECLARATION OF DAN SIMS UNDER 37 C.F.R. §1.132

I, Dan Sims, declare as follows:

1. I am a Research & Development engineer at Advanced Bio Prosthetic Surfaces, Ltd. (“ABPS, Ltd.”).
2. I am a resident of the State of Texas residing in San Antonio, Texas.
3. I graduated from the University of Texas with a Bachelor of Science degree in Mechanical Engineering.
4. Prior to my employment at ABPS, Ltd., I worked in the manufacturing industry specializing in the machining, fabricating, and welding of carbon steel, stainless steel, and aluminum.
5. Since joining ABPS, Ltd. in October 2001, I have had four and a half (4 ½) years of experience in the stent arts. My areas of concentration at ABPS Ltd. include thin film process development for medical devices, specifically thin film post-deposition processing and applications.

6. I understand the subject matter described in EP 0 759 730 (hereinafter referred to as the “‘730 patent”), which was cited by the Examiner in the Office Action of March 31, 2006 to form the basis for a 35 U.S.C. §102(b) rejection against claims 1-6, 8-12, 15, 18-24, 26-27, 29-31, and 34-35 of pending U.S. Patent Application No. 10/672,695 (hereinafter referred to as the “‘695 application”).
7. I am aware of and understand that the ‘695 application generally relates to an implantable endoluminal graft.
8. More specifically, I understand that the pending claims of the ‘695 application are directed, in general, towards an implantable endoluminal graft made of, *inter alia*, a metal thin film covering having a pattern of microporous openings passing therethrough.
9. As a person skilled in the stent arts, it is my opinion that the ‘730 patent to Burmeister does not suggest microporous openings formed onto a metal thin film, as described in the ‘695 application. Simply put, the Burmeister stent’s interstices (characterized by the Examiner as “elongated slots”) are too large to be characterized as “microporous”, as commonly understood by those skilled in the stent arts.
10. It is my further understanding that the openings, illustrated in the ‘730 patent and construed by the Examiner to be “microporous,” are in fact stent interstices. As widely known in the stent arts, interstices on a stent are structurally and functionally different from microporous openings on a graft (i.e., metal thin film covering). The size difference between interstices on a stent and microporous openings on a graft is immense, as evidenced by the micrograph designated as Exhibit A. Exhibit A illustrates a graft covering a conventional stent (i.e. structural support element). As shown in Exhibit A, whereas interstices on a conventional stent are sized in millimeter dimensions, microporous openings on a stent graft are typically sized in micrometer dimensions.

11. The microporous metal thin film covering described in the '695 application facilitates endothelialization of a stent by promoting cellular migration into microporous openings. By facilitating the endothelialization of the stent, incidence of restenosis can be greatly reduced.
12. As a skilled artisan in stent technology, from reviewing the '730 patent, it is my opinion that the stent described therein is not capable of promoting cellular migration into microporous openings.
13. Accordingly, it is my opinion that the stent interstices described in the '730 patent do not attain the microporous-sized dimensions of the graft openings described in the '695 application. Moreover, because the stent interstices described in the '730 patent are functionally and structurally different from the microporous openings described in the '695 application, it is my further opinion that the microporous openings in a graft, as described in the '695 application, are distinguished from the stent interstices taught by the '730 patent.
14. From my review of the '730 patent, it is also my opinion that the '730 patent does not disclose, expressly or implicitly, an affixation member, as described in the specification and the claims of the '695 application.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Dated: June 13, 2006



Dan Sims

Structural Support Element

Microporous Openings

Mathematics

Interstices

THE AMERICAN JOURNAL

Interstices

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EXHIBIT A